

# MAHARASHTRA POLLUTION CONTROL BOARD

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Scheme Road No. 8, Opp. Cine Planet Cinema, Near  
Sion Circle, Sion (E),  
Mumbai - 400 022

Red/L.S.I

Date: 30/11/2011

Consent No: BO/PAMS/E/EIC NO.RD-2182-11/CC- CAI-34

Consent to Establish under Section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

M/s Cipla Limited  
Plot no.A-2,MIDC Patalganga Dist-Raigad

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Establish of existing plant for renovation and replacement of building, plant & machinery is granted for a period up to: commissioning of the unit or 5 years whichever is earlier.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
1	Antihistaminic / Anti-Inflammatory Drugs :	17.0	MT/A
	Loraketone/Loratidine and its derivative OR Desloratadine and its derivatives of Fexofenadine hydrochloride and its derivatives Or Promethazine hydrochloride and its derivatives OR Celecoxib and its derivatives OR Etoricoxib and its derivatives OR Meloxicam and its derivatives or Rofecoxib and its derivatives OR Piroxicam and its derivatives OR Leflunomide and its derivatives OR Tramadole Hydrochloride and its derivatives OR Valdecoxib and its derivatives OR Parecoxib Sodium and its derivatives OR Divalproex Sodium and its derivatives OR Mometosone Furoate and its derivatives,		
2	Antidepressant Drugs	27.0	MT/A
	Fluxetine Hydrochloride and its derivatives OR Racemic Alcohol/Paroxetine Hydrochloride and its derivatives OR Venlafaxine Hydrochloride and its derivatives OR Bupropion Hydrochloride and its derivatives OR Citalopram Hydrobromide and its derivatives OR Duloxetine		



	Hydrochloride and its derivatives OR Reboxetine Methane Sulfonate and its derivatives OR Sertraline Hydrochloride and its derivatives		
3	<b>Hormones</b>	3.50	MT/A
	Mesterolone and its derivatives OR HPC and its derivatives OR Testosterone Enanthate and its derivatives OR Norethisterone and its derivatives OR Levonorgestryl and its derivatives OR Mifepristone and its derivatives.		
4	<b>Antibacterial / Antifungal / Antiviral Drugs</b>	52.0	MT/A
	Sulfamoxole and its derivatives OR Trimethoprim and its derivatives OR Ciprofloxacin and its derivatives OR Difloxacin and its derivatives OR Enrofloxacin and its derivatives OR Gatifloxacin and its derivatives OR Linezolid and its derivatives or Levofloxacin Hemihydrate and its derivatives OR Norfloxacin and its derivatives OR Ofloxacin and its derivatives OR Sparfloxacin and its derivatives OR Fluconazole and its derivatives OR Itraconazole and its derivatives OR Ketoconazole and its derivatives OR Terbinafine Hydrochloride and its derivatives OR Aciclovir and its derivatives OR Didanosine and its derivatives OR Efavirin and its derivatives OR Lamivudine and its derivatives OR Nelfinavir Mesylate and its derivatives.		
5	<b>Cardiac Drugs / Erectile Dysfunction</b>	25.0	MT/A
	Xanthinol Nicotinate and its derivatives OR Atorvastatin Calcium and its derivatives OR Fluvastatin Sodium and its derivatives OR Oxyfedrine Hydrochloride and its derivatives OR Pitavastatin and its derivatives OR Pravastatin Sodium and its derivatives OR Rosuvastatin Calcium and its derivatives OR Simvastatin and its derivatives OR Sildenafil Citrate and its derivatives OR Apomorphine and its derivatives.		
6	<b>Laxative / Anti Ulcerative Drugs</b>	127.0	MT/A
	Bisacodyl and its derivatives OR Normacol and its derivatives OR Famotidine and its derivatives OR Lansoprazole and its derivatives OR Omeprazole, Omeprazole Magnesium / Sodium and its derivatives OR Pantaprazole and its derivatives OR Rabeprazole and its derivatives.		
7	<b>Antihypertensive Drugs</b>	24.0	MT/A
	Clonidine Hydrochloride and its derivatives OR Di-Pyridamole and its derivatives OR Verpamil Hydrochloride and its derivatives OR Amlodipine Besylate / Maleate / Hydrochloride and its derivatives OR Atenolol and its derivatives OR Benzapril Hydrochloride and its derivatives OR Candesartan Cilexetil and its derivatives OR Carvedilol and its derivatives OR Diltiazem Hydrochloride and its derivatives OR Enalapril Maleate and its derivatives OR Irbesartan and its derivatives OR Lisinopril and its derivatives OR Losartan Potassium and its derivatives OR		



	Metolazone and its derivatives OR Ramipril and its derivatives OR S- Amlodipine Besylate and its derivatives OR Terazosin Hydrochloride Dihydrate and its derivatives		
8	<b>Anti-Asthmatic Drugs</b>	72.0	MT/A
	Theophylline and its derivatives OR Etofylline and its derivatives OR Diprophylline and its derivatives OR Montelukast Sodium and its derivatives.		
9	<b>Antiepileptic Drugs</b>	16.0	MT/A
	Carbamazepine and its derivatives		
10	<b>Anti Diabetic Drugs</b>	24.0	MT/A
	Sulphonamide / Glibenclamide / Glyburide and its derivatives OR Glimperide and its derivatives OR Pioglitazone Hydrochloride and its derivatives OR Repaglenide and its derivatives.		
11	<b>Antispasmodic Drugs</b>	6.0	MT/A
	Mebeverine Hydrochloride and its derivatives.		
12	<b>Anti Cancer / Antineoplastic Drugs</b>	1.0	MT/A
	Fosfestrol and its derivatives OR Cyclophosphamide and its derivatives OR Exemestane and its derivatives.		
	<b>Total</b>	<b>394.50</b>	

### 3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 318.00M<sup>3</sup>.  
(ii) The daily quantity of sewage effluent from the factory shall not exceed 50.00M<sup>3</sup>.  
(Industry shall achieve zero discharge of effluent as per their commitment)

#### (iii) Trade Effluent :

Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0
2	Suspended Solids	Not to exceed	100 mg/l.
3	BOD 3 days 27 deg C	Not to exceed	100 mg/l
4	COD	Not to exceed	250 mg/l.
5	Oil & Grease	Not to exceed	10 mg/l
6	TDS	Not to exceed	2100 mg/l.
7	Chlorides	Not to exceed	600 mg/l.
8	Sulphates	Not to exceed	1000 mg/l.
9	Total Ammonical Nitrogen	Not to exceed	50 mg/l.

- (iv) **Trade Effluent Disposal:** The treated trade effluent shall be 100 % recycle/reuse in the process only. Treated effluent shall not be used on land for gardening. These shall not be discharge within / outside factory premises.



(v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

(1)	Suspended Solids	Not to exceed	100	mg/l.
(2)	BOD 3 days 27o C.	Not to exceed	100	mg/l.

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1		Not applicable		

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under

The daily water consumption for the following categories is as under:

(i)	Domestic purpose	...	62.50	CMD
(ii)	Water gets Polluted & Pollutants are Biodegradable	...	185.50	CMD
(iii)	Water gets Polluted, Pollutants are not Biodegradable & Toxic	...	0.00	CMD
(iv)	Industrial Cooling, spraying in mine pits or boiler feed	...	173.00	CMD
(v)	Agriculture / Gardening	...	0.00	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT :**

(i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

a. **Control Equipment:**

- I. Scrubber of sufficient capacity shall be provided to source control process emission and dust collector of sufficient capacity shall be provided to boiler and all dust generating locations and operated properly.
- II. There shall not be any secondary (fugitive) emissions.

b. **Standards for Emissions of Air Pollutants:**

(i)	SPM/TPM	Not to exceed	150	mg/Nm <sup>3</sup>
(ii)	SO <sub>2</sub>	Not to exceed	117.0	Kg/day
(iii)	HCL	Not to exceed	35.0	mg/Nm <sup>3</sup>
(iv)	HBR	Not to exceed	35.0	mg/Nm <sup>3</sup>
(v)	NH <sub>3</sub>	Not to exceed	50.0	mg/Nm <sup>3</sup>



## 6. Conditions for D.G. Set

- a. Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- b. Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
- c. The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- d. Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use.
- g. D.G. Set shall be operated only in case of power failure.
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set

## 7. Standards for Stack Emissions:

- (i) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	Furnace Oil	1.30	MT /Day
	OR		
	Briquettes	6.00	MT /Day
2	HSD	1.0	KL/Day

- (ii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	30.00
2	D.G Set (100KVA)	3.5. ( above the roof)



- (iii) The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed. to facilitate identification.
- (iv) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.
- (vi) **Other Conditions:**
- 1) The industry should not cause any nuisance in surrounding area.
  - 2) The industry should monitor stack emissions and ambient air quality Regularly.

**8. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDARY MOVEMENT) RULES, 2008:**

- (i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	28.1 Residues and wastes*	16.00	MT	CHWTSDF
2	28.2 Off specification products	2.00	MT	CHWTSDF
3	33.1 Chemical-containing residue	14.00	MT	CHWTSDF
4	34.3 Chemical sludge from waste water treatment	10.00	MT	CHWTSDF

- (ii) Treatment: -NIL

9. Whenever due to any accident or gas leakage or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Collector, Directorate of Industry, Safety and Health, Police Station, Fire Brigade, Directorate of Health Services, Department of Explosives, Board and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emission and ensure that the emissions do not cause any harm or nuisance in the surrounding. The industry should not restart the process without permission of the Board and other statutory organization as require under the law.


**10. Industry shall comply with following additional conditions:**

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.



- iii. Solid waste – The non hazardous solid waste arising in the factory premises, sweepings, etc., be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
  - iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.
  - v. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent / emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.
  - vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
  - vii. The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
  - viii. The firm shall submit to this office, the 30<sup>th</sup> day of September every year, the Environmental Statement Report for the financial year ending 31<sup>st</sup> March in the prescribed Form-V as pre the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
  - ix. As inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
  - ix. The applicant shall install a separate electric meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
  - Xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.
  - xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
11. This consent shall not be construed as any exemption from obtaining necessary No Objection Certificate from other Government agencies as may deemed fit necessary.
  12. If CETP does not operate efficiently and problem of pollution occurs, industry should voluntarily stop the production or total effluent should reuse.

13. This consent is granted pursuant to the Rule (6) of RRZ Policy 2009, regarding modernization / expansion / change in product mix.
14. This consent is issued as per the decision taken in the meeting of the Consent Appraisal Committee of the Board held on 22/11/2011.
15. The applicant shall obtain consent to operate before starting actual commercial Production.
16. This consent is issued with an override effect to the earlier consent to operate vide No. BO/RO/Raigad /PCI-I/EIC No RD-1361-10/R/CC-77 dated 28/40/2010 valid up to 31.12.2013.
17. The Capital investment of the industry is Rs 160.00 Crore

  
24-11  
(Milind Mhaiskar)  
Member Secretary

To,  
M/s Cipla Limited  
Plot no.A-2,MIDC Patalganga Dist-Raigad

Copy to :  
RO,Raigad /SRO, Raigad I  
-- They are directed to ensure the compliance of consent conditions.  
CAO/Cess Branch/Master file.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	640000/-	39583	19 Nov 2010	Axis Bank